ALTIUS PHARMACS

MDs
for Consulting and Medical Writing
in Clinical Research and Medical Affairs

Established in 2001

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ALTIUS PHARMACS

- Providing Consulting, Coordination and Medical Writing Services to:
  - Development
  - Clinical Trials
  - Regulatory Affairs
  - Market Access
  - Medical Affairs
  - Business Developement
  - Quality
  - Transitional Management

A team of MDs
connected to clinical and non-clinical experts

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Research Tax Credit

ALTIUS PHARMA CS is approved as a private organization for research according to section II d bis of article 244 quater B of the French General Tax Code (Year 2014-2016)

Development

Development

- Strategic Analysis
- Clinical Development plan
- Coordination : CMC / Preclinical Research / Proof of concept / Clinical Research
- Study Design
- Project Management
- Feasibility Studies

Clinical Trials

Clinical Trials

- Protocol Design
- Scientific Committee set up and Management (Steering Committee, Data and Safety Monitoring Board)
- Regulatory Coordination for trial initiation (IMPD, Investigator's Brochure, informed consent and other study related documents)
- Specifications definition for tenders
- Selection / Supervision of CROs
- Clinico-Statistical Coordination
- Writing of ICH clinical study reports

Regulatory Affairs

Regulatory Affairs

From clinical studies to drug registration

- Advice on registration procedures and priority assessment strategy: Breakthrough Therapy, Fast Track, Priority Review and Accelerated Approval for FDA, PRIME (PRIority Medecine) Scheme for EMA
- Organisation of scientific advice(s) with regulatory agencies (National, Agency, EMA, FDA)
- Bibliographic applications or abridged applications (e.g. generics)
- Orphan Drug designation
- Pediatric Investigation Plan (PIP)
- Marketing authorization 5-yearly renewal

Regulatory Affairs

Common Technical Document

Quality and non-clinical safety modules

- CTD relevant section writing coordination (modules 2.3, 2.4 and 2.6)
- Data collection (study reports)
- Preparation of modules 3 and 4

Efficacy modules

- Writing of CTD relevant modules (2.5, Clinical Overview and 2.7, Clinical Summary)
- Preparation of module 5

Regulatory Affairs

Risk Management Plan

- Préparation of RMP in relationship with appliquant
- Definition of risks
- Epidemiologic search
- Document preparation

Market Access

Market Access

- Epidemiologic Research (literature reviews and analyses)
- Preparation of Technical File for Reimbursement (French Transparency Commission, French CNEDiMTS, NICE…)
- Scientific Board set up and Scientific Secretariat

Medical Affairs

Medical affairs

Post-launch follow-up

- Medical Input for Life Cycle Management
- Benefit / Risk report
- Risk Management Plan
- Re-assessment of « SMR » following French Transparency Commission Request

Medical Affairs

Scientific Communication and Training

- Manuscripts, Posters, Slides Writing
- Training Documents (internal and external) writing
- Product Monograph Writing

Medical Affairs

Boards of experts / Scientific Advisory Board

- Opinion Leaders Coordination for Medical Symposia
- Speakers Training
- Scientific Board Secretariat
- Congress Reports

Medical Affairs
Pharmacovigilance

- Writing of PSURs and DSURs

Business Development / Dossiers analysis

Business Development / Dossiers analysis

- Dossiers Analysis for Purchase / Licensing (Product Assessment, Scientific Analysis of the Medical Field, of the Disease and of the Competitors)
- Due-Diligence

Quality

Quality

- Development of Quality Systems
- Writing and Review of Quality Documents

Transitional Management

Transitional Management

- Management Support, Replacement or Starting up of a team
- Operational Team Management (Clinical Operations, Project Management)

Domains

Domains

- Medicinal products (all therapeutic domains)
- Biotechs (cell therapies, vaccines, …)
- Medical devices (equipment, dialysis solutions…)
- Cosmetics
- Food supplements

Clients

Clients

3M Santé
Abbott
Abbvie
ALK-Abelló
Amgen
Amring
Arrow France
Astellas
Bailly-Creat
Baxter
Besins international
BioAlliance Pharma/Onxeo
Biogen Idec
Bristol-Myers Squibb
Chemo/Exeltis
Chiesi
CSL Behring
DNDi
Exelgyn
Expanscience
Ferring
Fresenius Biotech
Fujisawa
Gambro
GSK
Horama
Ipsen Pharma
Janssen Cilag Int.
Labcatal
Laboratoires Genevrier
LFB Biotechnologies
L'Oreal
Lundbeck
Merck Génériques
Mylan
Negma-Lerads
Nordic Pharma
Norgine
Nutriset
Nycomed
Orfagen
OSE Pharma SA
OTL-Strakan
Pfizer
Pierre Fabre
Sanofi
Snitem
Stallergenes
Therabel
Theraclion
UPSA
Wyeth